

Navajo Nation Human Research Review Board

Meeting Agenda

Meeting Date: 2022-10-18 Meeting Time: 9:00 AM
Location: Zoom

MEMBERS:

Beverly Becenti-Pigman - Community
David Begay, Ph.D. - Scientific Education
Delvin Yazzie, MPH - Epidemiology
Kalvin White, Ph.D. - Scientific Education
Nanibaa' Garrison, Ph.D. - Genetics, Bio-Ethics
Rebecca Izzo-Manymules, Ph.D. - Chairperson - Education
Sonya Shin, MD - Medicine
Ursula Knoki-Wilson, MSN, MPH - Nursing

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OLD BUSINESS:

I. Meeting Call to Order:

II. Roll Call:

- Invocation:

- Introductions:

III. Review and Approval of Agenda:

IV. Review and Approval of May 17, 2022 Meeting Minutes:

NEW BUSINESS:

V. Review and Approval of Quarterly Reports:

VI. New Presentations:

VII. Returning Presentations:

VIII. Serious Adverse Events (SAEs):

IX. Noon Hour Discussion:

X. Review and Acceptance of Manuscripts: 1) Group Randomized Trial of Healthy Eating and Gardening Intervention in Navajo Elementary schools (Yeego!) (NNR-19.333). Dr. Lombard, 2) Inspiring Culturally Responsive Curriculum through Language Arts Seminars: A Reflection on Work during the Dine Institute for Navajo Nation Educators (NNR-19.359). Dr. A. Castagno, 3) urveillance of COVID-19 in Schools that Serve

Native American Communities (NNR-21.419). Dr. Allison-Burbank, 4) Din'e Teachings and Public Health Students Informing Peers and Relatives about Vaccine Education (RAVE): Providing Din'e (Navajo) centered COVID-19 education materials using student health messengers (NNR-18.302) Dr. M. Bauer; 5) A Qualitative Study on Factors Influencing Access to Autism Services For Din'e (Navajo) Parents -(NNR-20.389) Dr. O. Lindly

XI. Announcements and Adjournment:

QUARTERLY REPORTS

1. NNR-02.110 PI: Vallabh Shah
Diabetes Prevention Program Outcomes Study (DPPOS)
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1, 2022 - September 30, 2022 period

2. NNR-05.175 PI: Kimberly Mohs
Navajo Area Indian Health Services - Cardiovascular Risk Reduction Demonstration Project
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering June 1, 2022 - October 1, 2022 period

3. NNR-15.231 PI: Sara Selig
Engaging Patients and Stakeholders to Improve Cancer Outcomes in Navajo Nation
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering June 15, 2022 - September 15, 2022 period

4. NNR-16.234 PI: Karletta Chief
To Litso, the water is Yellow: Investigating short term exposure and risk perception of Navajo communities to the Gold King Mine toxic spill
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July - September 2022 period

5. NNR-17.287 PI: Hannah Sehn
Understanding the Structural Barriers and Opportunities to Improve Cancer Treatment on Navajo Nation
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering June 15, 2022 - September 15, 2022 period

6. NNR-18.309 PI: Christine Buzinde
Cultural Mapping for the Western Area Tribal Parks includingg the Former Bennett Freeze Area
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July 1, 2022 - September 30, 2022 period

7. NNR-18.330 PI: Laurie Hudson
Thinking Zinc
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report coveing April 22, 2022 - July 21, 2022 period

8. NNR-19.349 PI: Tasha Seneca Keyes

Restorative Justice practices for improving school-based relationships

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 20, 2022 - September 30, 2022 period

9. NNR-21.397T PI: Manley Begay, Jr.

Understanding Resilience and Mental Wellbeing: Southwest Indigenous Nations and the Impact of COVID-19

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 25, 2022 - September 24, 2022 period

10. NNR-21.414 PI: Laura Hammitt

Phase 3 Master Protocol to Evaluate additional Dose(s) of BNT162B2 in Healthy Individuals previously Vaccinated with BNT162B2

Reason on Agenda: (Other)

Description: Request Acceptance and Acknowledge MedWatch Safety Report (202200012540) for June 20, 2022 and June 24, 2022.

11. NNR-22.436 PI: Franklin Sage

The Changing Landscape and Climate of Dine'tah

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering March - June 2022 period

NEW PRESENTATION(S)

1. NNR-21.430 PI: Elise Christopher

High School & Beyond Longitudinal Study of 2022 (HS&B:22)

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study - TABLE at 9-27-22 meeting -Submit with required documents.; Date Received - 11/03/2021

2. NNR-22.450 PI: Candi Running Bear

Culturally Relevant Dialogic Reading to Increase Vocabulary in Navajo Preschoolers with Disabilities

Reason on Agenda: Revised Protocol

Description: Request Review and Approval of New Submission - TABLE at 9-27-22 Meeting, Re-submit with condition request.

3. NNR-22.453 PI: Katherine Speirs

Baby College 101: Courses for Alchini Yazhi Program Evaluation

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submissio; Date Received - 10/05/2022

4. NNR-22.454 PI: Elana Begay

How do Tribal Judges Understand Indigenous Peacemaking as Crime Control Tools, and their Varying Notions of Accountability

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission; Date Received - 10/05/2022

5. NNR-22.455 PI: Christina Andrade

Experiences of Effecting Persistence to Degree for Students attending Navajo Technical University During COVID-19

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission; Date Received - 10/06/2022

6. NNR-22.456 PI: Dornell Pete

Navajo ABID Study II: Helicobacter pylori risk and treatment experiences in Navajo Adults

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission; Date Received - 10/10/2022

RETURNING PRESENTATION(S)

1. NNR-20.384 PI: Dornell Pete

Assessing the Gut MicroBiota and Individual Diet in the Navajo ('Abid Study)

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report and Close-out Study covering October 2020 - October 2022 study period

2. NNR-18.312 PI: Laura Brown

Lactation and Technology for Community Health (LATCH)

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final Report covering August 21, 2018 - August 16, 2022 period. enclosed is Published manuscript and Raw data. TABLED at 9-27-22 Meeting

3. NNR-09.241 PI: Barbara Overman

Giving Voice to Health Values from within the Navajo Culture

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) May 1, 2021 - July 1, 2021; 2) August 1, 2021 - October 31, 2021; 3) November 1, 2021 - January 31, 2022; 4) February 1, 2021 - April 31, 2022; 5) May 1, 2022 - July 31, 2022 periods

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Reports covering: 1) July 31, 2020 - August 1, 2021, 2) July 31, 2021 - August 1, 2022 periods

4. NNR-11.323 PI: Johnnye Lewis

Navajo Birth Cohort Study (NBCS)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 23, 2022 - August 23, 2022 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 23, 2021 - August 22, 2022 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval Continuation Request covering August 23, 2022 - August 23, 2023 period

5. NNR-19.360 PI: Debra MacKenzie

Navajo Birth Cohort Study/environmental Influences on Child Health Outcomes Plus (NBCS/ECHO+)

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 18, 2020 - September 17, 2021 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 18, 2022 - September 17, 2022 period

Reason on Agenda: Modification

Description: Request Acceptance and Approval of Protocol Modification and Consent Form to adjust the amount of Blood collected from older children >3 from 1 tsp (5 mls) to approximately 1 tsp (15 mls)

6. NNR-16.257 PI: Kevin Lombard

Engaging Family and School in Navajo Gardening for Health

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 22, 2022 - September 20, 2022 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 21, 2021 - September 20, 2022 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of continuation Request covering September 21, 2022 - September

September 19, 2023 period

7. NNR-17.281 PI: Nanibaa' Garrison

Perspectives on Genetic Research in the Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 17, 2022 - August 16, 2022 period

Reason on Agenda: (Other)

Description: Request Acceptance and Approval to add new Research Assistant, Kaia Aagaard.

Reason on Agenda: Approval for Dissemination

Description:

Request Acceptance and Approval for Dissemination - Deliberation Report.

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approva of Powerpoint Presentation Titled "Examining Perspectives of Researchers Regarding Genetic Research on the Navajo Nation" at A) NN Genetic Policy Development Working Group-Virtual, Date TBA, B) NN HEHS Committee -virtual on TBA, C) National Diversity in STEM SACNS Nation Conferal - in-person on October 27-29, 2022, D) Human Medical Genetics and Genomics Retreat - in-person on November 3-4, 2022, E) Full Circle Symposium - in-person on November 17-18, 2022.

8. NNR-17.288 PI: Dana Dabelea

Tribal Turning Point (TTP)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July - September 2022 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 16, 2021 - October 16, 2022 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering October 16, 2022 - October 16, 2023 period

9. NNR-19.337 PI: Crystal LoudHawk-Hedgepeth

Kresge Inquiry Project

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering January 2022 - September 28, 2022 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering January 1, 2023 - December 31, 2023 period

10. NNR-19.359 PI: Angelina Castagno

Strengthening Teaching in Native Serving Schools Through Long-Term, Culturally Responsive Professional Development

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering September 18, 2021 - September 18, 2022 period

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Two (2) Abstracts Titled: 1) Teacher-Authored Culturally responsive Mathematics Curriculum: Lessons from the Din'e Institute for Navajo Nation Educators' at American Educational Research Association (AERA), in April 2023, 2) Promoting culturally responsive STEM education in Indigenous serving schools through in-service teacher professional development at the National Association of Research in Science Teaching (NARST) in April 2023 meeting

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering September 18, 2022 - September 18, 2023 period

11. NNR-21.412 PI: Joel Gittelsohn

Formative Research to Improve WIC Participation in Three Diverse Native American Communities

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering June 15, 2021 - June 15, 2022 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering June 15, 2022 - June 15, 2023 period

12. NNR-21.425 PI: Wayne Morgan

Healthy Hooghans Pilot Project

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering October 19, 2021 - October 18, 2022 period

13. NNR-20.380 PI: Regina Eddie

Examining School Wellness in American Indian Communities

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract for 3rd International Indigenous Nursing Research Summit, on

November 4-5, 2022 at University of Texas AT&T Conference Center.

14. NNR-14.185 PI: Sheldwin Yazzie

Assessing Indoor Radon Exposure on the Navajo Nation.

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 30, 2021 - July 30, 2022 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering 1) February 1, 2022 - April 30, 2022; 2) May 1, 2022 - July 31, 2022, period

15. NNR-15.223 PI: Jennifer Richards

Formative Research to Inform the Development of an Intergenerational Strengths-Based Program for American Indian Girls as they Transition to Adulthood.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of to amend inclusion criteria based on race and ethnicity to ensure target population is not excluded, permission to use a new postcard flyer, new 2 sided, Center name change to Johns Hopkins Center for Indigenous Health and new logo.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of reconsenting process by electronically via REDCap.

16. NNR-19.364 PI: Jennifer Richards

Replication of Respecting the Circle of Life (RCL) - Teen Pregnancy Prevention Program with Navajo Youth and Families

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering November 19, 2022 - November 19, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering November 21, 2021 - November 19, 2022 period

17. NNR-21.401 PI: Jennifer Richards

Evaluation of Azhee Bidziil (Strong Fathers) Program: Improving Outcomes Among Rural Fathers and their Families.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to Revise 1) Initial Contact Form, 2) Research Plan and Adult Father/Male Caregiver Informed Consent Form; New document) 3) Postcard Mailing Flyer

18. NNR-20.381 PI: Laura Hammitt

A Phase 1/2/3 Placebo-Controlled, Randomized, Observer-Blind, Dose-Find Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARs-COV 2 RNA Vaccine Candidates Against COVID-19 in Healthy Adults (Short Title: Pfizer COVID-19 Vaccine Study)

Reason on Agenda: (Other)

Description: Request Acceptance and Acknowledge MedWatch Safety Report (202200012540) for June 20, 2022 and June 24, 2022.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment of Revised Documents: 1) added language pertaining to early completion of this clinical trial as agreed with Food and Drug Administration and European Medical Agency: update schedule of assessment, update study procedure. 2) Removed the objective to describe the safety and immunogenicity of prophylactic BNT162b2, remove corresponding endpoints, remove corresponding wording throughout protocol text, added rationale for removal of this objectives. 3) added wording return of e-diary devices or removal of application from participants personal devices at end Study.

19. NNR-15.232 PI: Laura Hammitt

Etiology of pneumonia and burden of pneumococcal pneumonia in hospitalized American Indian adults

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request Covering November 17, 2022 - November 17, 2023 period

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering November 17, 2021 - November 17, 2022 period

20. NNR-16.264 PI: Allison Barlow

Preventing Early Childhood Obesity, Part I: Family Spirit Nurture, 3-9 Months, Part II: 18 Months

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract for poster presentation Titled: Family Spirit Nurture: An Indigenous Solution for Promoting Healthy Infant and Family Nutrition. (Part I 3-9 Months)

21. NNR-21.431 PI: Allison Barlow

Evaluation of Navajo Safe Water Access Projects

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to modify research plan, update consent forms and recruitment materials, new Center name (Johns Hopkins Center for Indigenous Health) increase sample size, focus group. Chapter Flyer, Community Member flyer.

22. NNR-21.419 PI: Joshuaa Allison-Burbank

Project Safe Schools: Re-opening schools serving Native children and adolescents SAFELY

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of 3 Amendments: 1) Update and Correct Parent Caregiver Survey errors;
2) Survey Study Completion Certificate both Parents and School Staff; 3) Study Completion Script.

23. NNR-22.445 PI: Joshuaa Allison-Burbank

Piloting + Connection is Medicine

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments to update Research Plan to add TextIt as a Non-JHU
Management Platform

24. NNR-21.397T PI: Manley Begay, Jr.

Understanding Resilience and Mental Wellbeing: Southwest Indigenous Nations and the Impact of COVID-19

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request coverin December 31, 2022 - December 31, 2023
period

SERIOUS ADVERSE EVENT

1. NNR-20.374 PI: Laura Hammitt

Immunogenicity of H, Influenzae type b PRP-OMP vaccines in American Indian and Alaska Native Children (the
HibVax Study)

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Acute hypoxemic respiratory distress due to COVID induced bronchiolitis and croup

2. NNR-20.381 PI: Laura Hammitt

A Phase 1/2/3 Placebo-Controlled, Randomized, Observer-Blind, Dose-Find Study to Evaluate the Safety,
Tolerability, Immunigenicity, and Efficacy of SARs-COV 2 RNA Vaccine Candidates Against COVID-19 in Healthy
Adults (Short Title: Pfizer COVID-19 Vaccine Study)

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Alcoholic cirrhosis and gastrointestinnal bleed

Last Page and End of Agenda

